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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/693,754

10/20/2000

Neil Berinstein

13115

7885

7590

05/18/2006

AVENTIS PASTEUR
DISCOVERY DRIVE
SWIFTWATER, PA 18370

EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,754

Applicant(s)

BERINSTEIN ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, and 4-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's petition to revive this application, previously abandoned on 8/11/05, was granted on 2/23/06. As a result of the petition decision, applicant's amendment received on 11/07/05 has been entered. Claims 1-2, and 4-27 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in the instant action can be found in the previous office action.

Claim Rejections - 35 USC 103

The rejection of claims 1-2, 4-17, and 20 under 35 U.S.C. 103(a) as being unpatentable over Hurpin et al. (1998) Vaccine, Vol. 16 (2/3) 208-215, in view of Hodge et al. (1997) Vaccine, Vol. 15, No. 6/7, 759-768, US Patent No. 6,127,116 (10/3/00), filed on 3/4/97 and hereafter referred to as Rice et al., and Lehner et al. (1999) J. Infect. Dis., Vol. 179 (Suppl 3), S489-S492, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant has not provided any arguments regarding the teachings of Hurpin et al. or Hodge et al. The applicant argues that neither Rice et al. nor Lehner et al. supplement Hurpin or Hodge by providing the requisite suggestion and reasonable expectation of success for

generating immune responses according to the instant methods claimed by using administration into a lymph node. The applicant argues that Rice only provides a laundry list of possible routes of administration, one of which includes administration to lymph nodes, and that this is not sufficient to motivate the artisan to use lymph node administration. In response, it is clear from the indicated passage from Rice reproduced in the applicant's response that Rice does more than just include lymph node administration in a "laundry list" of administration routes. Rice in fact teaches that administration directly or indirectly to lymph nodes is a preferred method of immunization. Thus, of the genus of parenteral routes taught by Rice, Rice specifically points to the use of lymph node administration. Therefore it is maintained that Rice does in fact provide specific motivation for lymph node immunization.

Regarding the required "reasonable expectation of success", the applicant argues that at best Rice only provides an invitation to try lymph node administration and Lehner does not supplement Rice because the Lehner method teaches "in the proximity of" the iliac lymph nodes and does not teach administration "to" the iliac lymph node. In response, Rice already provides the motivation to generate immune responses by administering directly to a lymph node. Lehner provides a reasonable expectation that delivery of antigen to lymph nodes would prime an immune response by demonstrating the delivery of the antigen such that the lymph node is targeted generates increased immune responses to the antigen as compared to other routes of administration. As stated in the previous office action, Lehner et al. showed that a direct comparison of intramuscular versus intradermal versus targeted iliac lymph node immunization revealed that targeted iliac lymph node administration of antigen resulted in increased T and B cell mediated antigen-specific immune responses (Lehner et al., page S489, and page S491).

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Thus, by demonstrating that targeting antigen to the iliac lymph node results in increased T and B cell mediated antigen-specific immune responses over other routes of administration, Lehner et al. provides motivation for substituting lymph node administration as taught by Rice et al. over the intrasplenic or intramuscular administration routes taught by Hurpin et al. and Hodge et al.

Thus, for reasons of record, the rejection stands.

The rejection of claims 18-19 under 35 U.S.C. 103(a) as being unpatentable over Hurpin et al. (1998) Vaccine, Vol. 16 (2/3) 208-215, in view of Hodge et al. (1997) Vaccine, Vol. 15, No. 6/7, 759-768, US Patent No. 6,127,116 (10/3/00), filed on 3/4/97 and hereafter referred to as Rice et al., and Lehner et al. (1999) J. Infect. Dis., Vol. 179 (Suppl 3), S489-S492, as applied to claims 1-2, 4-17, and 20, and further in view of Zaremba et al. (1997) Canc. Res., Vol. 57, 4570-4577 and Salgaller et al. (1996) Canc. Res., Vol. 56, 4749-4757, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

Applicant's arguments are based on their previous argument that Hurpin in view of Hodge, Rice, and Lehner do not provide the requisite motivation and reasonable expectation of success to arrive at the instant invention as claimed. These arguments have been fully considered and addressed in detail above and have not been found persuasive. Applicant's further argument that Zaremba et al. and Salgaller et al. do not overcome the deficiencies of Hurpin, Hodge, Rice, and Lehner is not persuasive as the teachings of Hurpin, Hodge, Rice, and Lehner stand and Zaremba and Salgaller were not cited to teach lymph node administration, rather these references were cited to provide teachings and motivation to immunize with tumor antigens which comprise

the sequence YLSGADLNL or YLEPGPVTV. The applicant has not traversed these teachings, therefore, the rejection of record stands.

The rejection of claims 21-27 under 35 U.S.C. 103(a) as being unpatentable over Hurpin et al. (1998) Vaccine, Vol. 16 (2/3) 208-215, in view of Hodge et al. (1997) Vaccine, Vol. 15, No. 6/7, 759-768, US Patent No. 6,127,116 (10/3/00), filed on 3/4/97 and hereafter referred to as Rice et al., and Lehner et al. (1999) J. Infect. Dis., Vol. 179 (Suppl 3), S489-S492, as applied to claims 1-2, 4-17, and 20 above, and further in view of Barnett et al. (1997) Vaccine, Vol. 15(8), 869-873, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

Applicant's arguments are based on their previous argument that Hurpin in view of Hodge, Rice, and Lehner do not provide the requisite motivation and reasonable expectation of success to arrive at the instant invention as claimed. These arguments have been fully considered and addressed in detail above and have not been found persuasive. Applicant's further argument that Barnett does not overcome the deficiencies of Hurpin, Hodge, Rice, and Lehner is not persuasive as the teachings of Hurpin, Hodge, Rice, and Lehner stand and Barnett was not cited to teach lymph node administration, rather Barnett was cited to provide teachings and motivation to immunize using a prime/boost vaccination strategy which includes a priming step with a nucleic acid encoding an antigen and a boosting step with a protein form of the antigen. The applicant has not traversed these teachings, therefore, the rejection of record stands.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the

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USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'Dave', with a long horizontal line extending to the right.

Dr. A.M.S. Wehbé